IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):	Paul Re, et al.	EXAMINER:	Lindsey M. Bachman
SERIAL NO.:	10/812,609	GROUP:	3734
FILED:	March 30, 2004	DATED:	June 28, 2010
TITLE:	**APPARATUS AND METHOD FOR THE REPAIR OF ARTICULAR CARTILAGE DEFECT**		

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Commissioner for Patents
P.O. Box 1450
Alexandria, Va. 22313-1450

BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action dated November 24, 2009 and an Advisory Action dated February 16, 2010 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a/ Covidien) having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and/or the assignee of Appellants' interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings

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CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: June 28, 2010

Suzanne L. Forlani

which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The instant application was originally filed with 20 Claims. Claims 1, 3, 9, 16, 17 and 20-22, while Claims 2, 4-8, 10-15, 18 and 19 have been cancelled. Independent Claims 1 and 20 and dependent Claims 3, 9, 16, 17, 21 and 22 are pending in this application and are involved in this Appeal. Each of these Claims stands finally rejected as set forth in the Final Office Action mailed November 24, 2009 (the "Final Office Action") and the Advisory Action mailed February 16, 2010 (the "Advisory Action"). An accurate copy of Claims 1, 3, 9, 16, 17 and 20-22 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed February 16, 2010 indicates that the Request for Reconsideration filed on January 22, 2010 has been considered but does not place the application in condition for allowance. Thus, the claims are as presented in the Request for Reconsideration.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to an encapsulation device 5 for the repair of an articular cartilage defect. (Page 6, lines 11-13). The device includes a body 10 having a generally annular frame supporting therein a solid shell-like cover 14 portion for disposition adjacent a bone in an area of the cartilage defect. (Page 14, lines 15-17; page 22, lines 18-22; FIG. 1). The device further includes an elongated leg structure 25 having a plurality of elongated leg members, each

extending from a distal side of said body for disposition in the bone in the area of the cartilage defect. (Page 14, lines 18-19; FIG. 12). The leg members each have a length which is a plurality of magnitudes greater than a thickness of said body (page 14, lines 19-22; FIG. 1), and being of a generally conical configuration along substantially the length thereof. (Page 14, line 22- page 15, lines 2; FIG. 1). The annular frame includes a peripheral frame portion. (FIG. 1). The cover portion 14 is integral with the frame portion and is disposed within the frame. (FIG. 1). The cover portion 14 is bowed proximally to always provide a bowed proximal end profile for engagement by a complementary-shaped tool head 40, and adapted to maintain that profile during engagement of said body with the tool head 40. (Page 16, lines 6-8; FIGS. 3 and 4). Each of the leg members is provided with a central channel 30 therein. (Page 15, lines 6-8). Each of the channels 30 opens on a proximal side of the frame and extends substantially the length of each of the leg members to a point proximate a closed distal end thereof. (See FIGS. 3 and 4). At least one of the leg members is provided at a distal end thereof with an end portion enlarged beyond a periphery of the leg member at a proximal end of the end portion and a generally crested end portion 26 at a distal end of the end portion. (Page 21, line 22- page 22, line 5).

Claim 20 is directed to a method for effecting a repair to an articular cartilage defect. (Page 16, lines 4-6). The method includes the steps of providing an encapsulation device 5 including a body 10 for disposition adjacent a bone in an area of the cartilage defect and an elongated leg structure 25 having a plurality of elongated leg members extending from the body for disposition in the bone in the area of the cartilage defect. (Page 9, lines 6-13). The elongated leg structure includes legs provided with a central channel 30 therein. (Page 15, lines 6-8). The channel is open on a proximal side of the frame member and extends substantially the length of

each of the leg members to a point proximate a closed distal end thereof. (See FIGS. 3 and 4). The body 10 includes a peripheral circular frame portion and a solid shell-like cover portion 14 fixed within the frame portion. (Page 21, lines 16-19). The body is bowed proximally to provide a bowed proximal surface, such that a central portion of the cover portion always extends proximally further than a peripheral portion of the cover portion. (See FIGS. 3 and 4). The method further includes the steps of producing an elongated hole in the bone for each leg of the encapsulation device leg structure(page 9, lines 13-14; FIGS. 7 and 8), receiving a distal end of an insertion tool within the central channels of each of the leg members(page 16, lines 14-20; FIG. 10), and driving each leg of the leg structure of the encapsulation device into the hole provided therefore in the bone to bring a distal surface of the bowed encapsulation device body into adjacency with the bone. (Page 9, lines 14-18; FIG. 11).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are on appeal:

whether Claims 1, 3, 9, 16, 17 and 20-22 are obvious under 35 U.S.C. § 103(a) over U.S. Patent 6,267,772 to Mulhauser et al. ("Mulhauser") in view of U.S. Patent No. 4,776,328 to Frey et al.("Frey") and U.S. Patent No. 5,139,499 to Small et al. ("Small"); and

whether Claims 1, 3, 9 and 16 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 6,187,009 to Herzog et al. ("Herzog") in view of Small and Mulhauser.

VII. ARGUMENT

A. Mulhauser In View of Frey And Small Fails To Render Obvious The Recited Encapsulation Device Including Leg Members Each Having A Length Which Is A Plurality of Magnitudes Greater Than A Thickness Of The Body And Including A Central Channel Therein

Claims 1, 3, 9, 16, 17 and 20-22 stand rejected under 35 U.S.C. § 103(a) over Mulhauser in view of Frey and Small. Appellants respectfully submit that these rejections should be reversed.

1. Claims 1, 3, 9, 16, 17 and 21

Independent Claim 1 recites an encapsulation device for the repair of an articular cartilage defect. The device includes a body having a generally annular frame supporting therein a solid shell-like cover portion for disposition adjacent a bone in an area of the cartilage defect. The device further includes an elongated leg structure having a plurality of elongated leg members, each extending from a distal side of said body for disposition in the bone in the area of the cartilage defect. The leg members each have a length which is a plurality of magnitudes greater than a thickness of the body, and being of a generally conical configuration along substantially the length thereof. The annular frame includes a peripheral frame portion. The cover portion is integral with the frame portion and is disposed within the frame. The cover portion is bowed proximally to always provide a bowed proximal end profile for engagement by a complementary-shaped tool head, and adapted to maintain that profile during engagement of the body with the tool head. Each of the leg members is provided with a central channel therein. Each of the channels opens on a proximal side of the frame and extends substantially the length of each of the leg members to a point proximate a closed distal end thereof. At least one of the

leg members is provided at a distal end thereof with an end portion enlarged beyond a periphery of the leg member at a proximal end of the end portion and a generally crested end portion at a distal end of the end portion.

Mulhauser discloses an implantable prosthesis 10, shown in FIG. 2(a), reproduced below, for repairing and reinforcing a ruptured or defective muscular wall. Prosthesis 10 includes a pliable tissue infiltration fabric 12 and a semi-rigid frame 14. The flat implant is sufficiently pliable to allow the surgeon to roll the implant into a narrow cylinder which is suitable for loading into the lumen of a trocar. The implant may include spaced barbs 22 for preventing migration of the implant until tissue infiltration securely anchors the mesh relative to the rupture site.

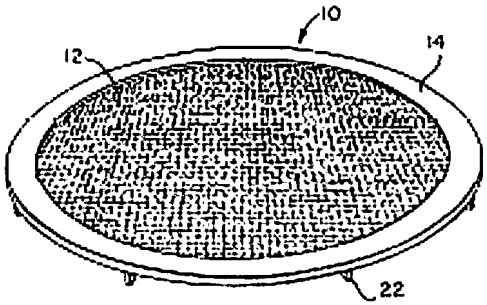

Fig. 2(a)

As conceded by the Examiner in the Final Office Action, Mulhauser fails to teach that the legs are several times longer than the thickness of the body, are generally conical or that the legs contain central channels. (Page 3, lines 17-19). The Examiner relies on Frey to teach that it is known to provide anchors that are substantially longer in order to provide a stronger connection with the tissue. (Page 4, lines 1-5).

With reference to FIG. 1 of Frey reproduced below, Frey discloses a bone nail 1 having a

cylindrical stem 3, a tapered portion 4 which extends from the stem 3 to a distal end, and a conical head 2 extending from the stem 3 to a proximal end. The tapered portion 4 includes a relatively fine denticulations 5 for penetrating cortical tissue when driven into a bone and a coarse denticulation 6 for anchoring the nail 1 in spongiosa.

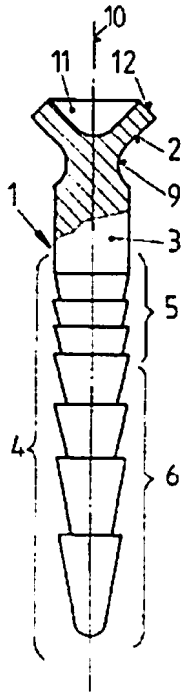

Fig.1

Contrary to the Examiner's assertion, it would not have been obvious to modify the prosthesis of Mulhauser to include the features of the bone nail of Frey. Modifying the prosthesis of Mulhauser to include the teachings of the bone nail of Frey would change the principle of operation of the prosthesis of Mulhauser. More specifically, the addition of elongated anchors intended to be secured in bone to the prosthesis of Mulhauser would prevent the use of the prosthesis in repairing soft tissue defects, i.e., tears or ruptures, as most soft tissue is not thick enough to accommodate the elongated legs.

In addition, the modification of Mulhauser's implant in view of Frey as suggested by the Examiner, would prevent Mulhauser's prosthesis from being rolled into a narrow configuration and thus, prevent Mulhauser's prosthesis from being loaded into the lumen of a trocar and inserted into a patient in the manner intended by Mulhauser. MPEP § 2143.01(VI) states that "[i]f the proposed modification of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claim *prima facie* "obvious." Furthermore, MPEP § 2143(V) states that "[i]f proposed modification would render the prior art being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." The inclusion of elongated anchors to the prosthesis of Mulhauser would not only prevent the use of the prosthesis in the repair of soft tissue defects because of the thickness of most soft tissue, the elongated anchors also prevent the rolling of the prosthesis for laparoscopic delivery, thereby nullifying the principle benefits of Mulhauser's prosthesis.

In addition, the Examiner also concedes in the Final Office Action, that the combination of Mulhauser and Frey fails to teach an anchor which includes a central channel that extends substantially the length of the anchor member. (Page 4, lines 6-7). The Examiner relies on Small to teach an anchor having a central channel configured for engaging a delivery device. (Page 4, lines 8-11).

With reference to Figs. 1 and 10 of Small reproduced below, Small discloses a screw 20 including a thread extending the length thereof. Screw 20 includes a blind axial bore 26 which extends from a proximal end of screw 20 to a central portion of screw 20 and is configured to receive a distal end 66 of a driver 50. Bore 26 enables screw 20 to provide positive rotational

engagement between screw 20 and driver 50. Screw 20 is configured to be rotationally received within a gap 106 formed between a bone plug 100 and the wall of a hole 102. In an alternative embodiment, screw 120 is configured to be received in a pilot hole 400 (Fig. 13 of Small).

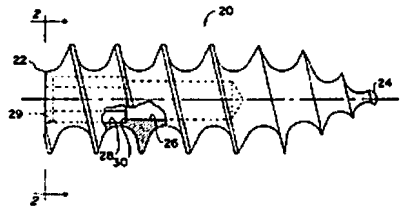

Fig. 1

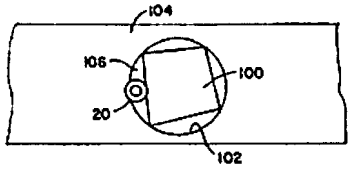

Fig. 10

Contrary to the Examiner's assertion, it would not have been obvious to modify the prosthesis of Mulhauser to include the features of the screw of Small. As discussed above with regards to the combination of the prosthesis Mulhauser and the bone nail of Frey, combining the screw of Small, configured for securing a bone plug with a hole in bone, with the prosthesis for soft tissue repair of Mulhauser would change the principle of operation of the prosthesis and would render the prosthesis unsatisfactory for its intended use in soft tissue repair.

Furthermore, unlike the prosthesis of Mulhauser, which includes fixed anchor means (barbs 22), driving the screw of Small into tissue requires, 1) a pilot hole or gap, and 2) a positive engagement between the screw and the driver to facilitate rotatable insertion of the screw into pilot hole or gap. A person of ordinary skill in the art of insertion devices would not look to the screw of Small which is configured to be axially rotated into a pre-drilled opening for disclosure of a driver engagement interface for a device, such as that disclosed by Mulhauser, because barbs 22 of Mulhauser are, 1) fixed to semi-rigid frame 14, and thus, cannot be rotated, and 2) are configured for attaching to soft tissue, and thus, are not configured for securement to bone.

Thus, Mulhauser in view of Frey and Small fails to render obvious Claim 1 and

Appellants submits that Claim 1 is in condition for allowance. For at least these same reasons, *inter alia*, Appellants submit that Claims 3, 9, 16, 17 and 21, which depend directly or indirectly from Claim 1, are also in condition for allowance. Therefore, Appellants submits that the rejection of Claims 1, 3, 9, 16, 17 and 21 under 35 U.S.C. § 103(a) should be reversed.

2. **Claims 20 and 22**

Independent Claim 20 is directed to a method for effecting a repair to an articular cartilage defect. The method includes the steps of providing an encapsulation device including a body for disposition adjacent a bone in an area of the cartilage defect and an elongated leg structure having a plurality of elongated leg members extending from the body for disposition in the bone in the area of the cartilage defect. The elongated leg structure includes legs provided with a central channel therein. The channel is open on a proximal side of the frame member and extends substantially the length of each of the leg members to a point proximate a closed distal end thereof. The body includes a peripheral circular frame portion and a solid shell-like cover portion fixed within the frame portion. The body is bowed proximally to provide a bowed proximal surface, such that a central portion of the cover portion always extends proximally further than a peripheral portion of the cover portion. The method further includes the steps of producing an elongated hole in the bone for each leg of the encapsulation device leg structure, receiving a distal end of an insertion tool within the central channels of each of the leg members, and driving each leg of the leg structure of the encapsulation device into the hole provided therefore in the bone to bring a distal surface of the bowed encapsulation device body into adjacency with the bone.

As discussed above, Mulhauser discloses a prosthesis for use in soft tissue repair. As

conceded by the Examiner, Mulhauser fails to disclose that the legs are several times larger than the thickness of the body, that the legs that contain central channels that extend partially through the legs and that the cover member is made of metal. (Page 5, lines 11-14). According to the Examiner, it would have been obvious to modify the prosthesis of Mulhauser to include legs that contain central channels to aid in engaging the leg with a deployment tool as disclosed by Frey. (Page 5, lines 15-21).

As discussed above, Frey discloses a bone nail. Modifying the prosthesis of Mulhauser to include the features of the bone nail of Frey would change the principle of operation of the prosthesis and would render the prosthesis unsatisfactory for its intended use in soft tissue repair. Thus, contrary to the Examiner's assertion, it would not have been obvious to modify the prosthesis of Mulhauser to include the features of the bone nail of Frey.

As conceded by the Examiner, the combination of Mulhauser and Frey fails to disclose a leg structure with a central channel that extends substantially the length of the leg. (Page 6, lines 1-2). According to the Examiner, it would have been obvious to modify the prosthesis of Mulhauser in view of Frey with the teachings of Small to disclose such a feature. (Page 6, lines 3-6).

As discussed above, Small discloses a screw for securing a bone plug in a hole drilled in bone. Modifying the prosthesis of Mulhauser to include the features of Small would change the principle of operation of the prosthesis and would render the prosthesis unsatisfactory for its intended use in soft tissue repair. Furthermore, unlike the prosthesis of Mulhauser, which includes fixed anchor means, driving the screw of Small into tissue requires, 1) a pilot hole or gap, and 2) a positive engagement between the screw and the driver to facilitate rotatable

insertion of the screw into pilot hole or gap. A person of ordinary skill of the art of insertion devices would not look to the screw of Small which is configured to be axially rotated into a pre-drilled opening for disclosure of a driver engagement interface for a device, such as that disclosed by Mulhauser, because barbs 22 of Mulhauser are, 1) fixed to semi-rigid frame 14, and thus, cannot be rotated, and 2) are configured for piercing soft tissue, and thus, are not configured for securement to bone.

Thus, Mulhauser in view of Frey and Small fails to render obvious Claim 20 and Appellants submits that Claim 20 is in condition for allowance. For at least these same reasons, *inter alia*, Appellants submit that Claim 22, which depends directly from Claim 20, is also in condition for allowance. Therefore, Appellants submits that the rejection of Claims 20 and 21 under 35 U.S.C. § 103(a) should be reversed.

B. Herzog In View of Frey And Mulhauser Fails To Render Obvious The Recited Encapsulation Device Including A Body Having A Generally Annular Frame And Leg Members Each Having A Central Channel Therein

Claims 1, 3, 9 and 16 stand rejected under 35 U.S.C. § 103(a) over Herzog in view of Frey and Mulhauser. Appellant respectfully submits that these rejections should be reversed.

As discussed above, independent Claim 1 recites an encapsulation device for the repair of an articular cartilage defect, including, *inter alia*, "a body having a generally annular frame leg members" and "an elongated leg structure comprising a plurality of elongated leg members... each of the leg members is provided with a central channel therein, each of the channels opening

on a proximal side of said frame and extending substantially the length of each of said leg members to a point proximate a closed distal end thereof."

With reference to FIG. 1 of Herzog reproduced hereinbelow, Herzog discloses an implant for joining bone fragments. The implant includes a body 1 in the form of a plate, e.g., rectangular, and a pair of extensions 4 extending from body 1. The thickness of the plate-shaped body 1 decreases continuously from a center 7 toward a periphery 8. Each of extensions 4 includes outer surfaces 5 provided with retaining structure 9 in the form of truncated conical sections which widen in the form of a cone toward a lower side.

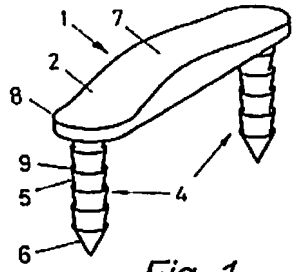

Fig. 1

With reference to FIG. 5 of Herzog, extension 4 may include a hollow body design with a central channel 10 into which a spreading body 13 can be inserted to spread the extension 4 with its retaining structure 9 in bone.

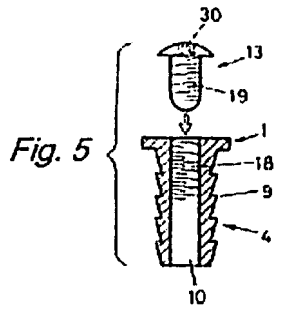

Fig. 5

As conceded by the Examiner, Herzog does not disclose conical legs including a central

channel that is closed at the distal end or an annular frame. (Page 6, lines 20-21). The Examiner relies on Small to disclose providing a leg structure with a central channel in order to engage with a delivery device (page 7, lines 1-4) and on Mulhauser to provide an annular shaped body for the purpose of providing better structural support (page 7, lines 5-8).

As discussed above, Small discloses a screw for securing a bone plug within a hole drilled in bone. Unlike the implant of Herzog, which includes fixed extensions for securing the implant to bone, the screw feature of the screw of Small requires a positive engagement between the screw and the driver to facilitate rotatable insertion of the screw. A person of ordinary skill of the art of insertion devices would not look to the screw of Small which is configured to be axially rotated into a pre-drilled opening for disclosure of a driver engagement interface for a device, such as that disclosed by Herzog, because extensions of Herzog are fixed to the body, and thus, cannot be rotated.

The Examiner relies on Mulhauser to teach an annular body for providing better structural support and on Small to teach an anchor having a central channel configured for engaging a delivery device. (Page 7, lines 5-9). As discussed above, Herzog is configured for joining bone fragments. A person of ordinary skill in the art of bone repair would not look to the prosthesis of Mulhauser, which is configured for soft tissue repair, for disclosure of an annular frame. Specifically, modifying the rigid implant of Herzog which is configured to prevent movement of multiple bone segments relative to each other with the flexible prosthesis of Mulhauser would change the principle of operation of Herzog's implant and would render the implant unsatisfactory for its intended use in joining bone fragments.

Thus, Herzog in view Small and Mulhauser fails to render obvious Claim 1 and

Appellants submits that Claim 1 is in condition for allowance. For at least these same reasons, *inter alia*, Appellants submit that Claims 3, 9 and 16, which depend directly or indirectly from Claim 1, are also in condition for allowance. Therefore, Appellants submit that the rejection of Claims 1, 3, 9 and 16 under 35 U.S.C. § 103(a) should be reversed.

C. Conclusion

In view of the foregoing analysis and remarks, it is clear that the encapsulation device for the repair of an articular cartilage defect recited in independent Claims 1 and the method for effecting a repair to an articular cartilage defect of Claim 20 is not obvious over Mulhauser in view of Frey and Small, and the method for effecting a repair to an articular cartilage defect of Claim 20 is not obvious over Herzog in view of Small and Mulhauser.

For at least the foregoing reasons, it is respectfully submitted that:

Claims 1, 3, 9, 16, 17, 20-22 are not rendered obvious under 35 U.S.C. § 103(a) over Mulhauser in view of Frey and Small, and this rejection should be reversed; and

Claims 1, 3, 9 and 16 are not render obvious under 35 U.S.C. § 103(a) over Herzog in view of Small and Mulhauser and this rejection should be reversed.

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VIII. CLAIMS APPENDIX

1. An encapsulation device for the repair of an articular cartilage defect, the device comprising:

a body having a generally annular frame supporting therein a solid shell-like cover portion for disposition adjacent a bone in an area of the cartilage defect;

an elongated leg structure comprising a plurality of elongated leg members, each extending from a distal side of said body for disposition in the bone in the area of the cartilage defect, said leg members each having a length which is a plurality of magnitudes greater than a thickness of said body, and being of a generally conical configuration along substantially the length thereof;

said annular frame comprising a peripheral frame portion, and said cover portion being integral with said frame portion and disposed within said frame and of a configuration bowed proximally to always provide a bowed proximal end profile for engagement by a complementary-shaped tool head, and adapted to maintain that profile during engagement of said body with the tool head; and

each of said leg members being provided with a central channel therein, each of the channels opening on a proximal side of said frame and extending substantially the length of each of said leg members to a point proximate a closed distal end thereof;

wherein at least one of said leg members is provided at a distal end thereof with an end portion enlarged beyond a periphery of said leg member at a proximal end of the end portion and a generally crested end portion at a distal end of the end portion.

2. (Cancelled).

3. The device in accordance with claim 1 wherein each of said leg member end portions comprises a circumferential protrusion thereon for gripping the bone.

4-8. (Cancelled).

9. The device in accordance with claim 1 wherein said peripheral frame portion bounds said cover portion.

10-15. (Cancelled).

16. The encapsulation device in accordance with claim 1 wherein the device is of a selected one of (i) bioabsorbable material and (ii) bioremodelable material.

17. The encapsulation device in accordance with claim 1 wherein the device is impregnated with cell growth material.

18-19 (Cancelled).

20. A method for effecting a repair to an articular cartilage defect, the method comprising the steps of:

providing an encapsulation device comprising a body for disposition adjacent a bone in an area of the cartilage defect, and an elongated leg structure comprising a plurality of elongated

leg members extending from the body for disposition in the bone in the area of the cartilage defect, the elongated leg structure comprising legs, each leg provided with a central channel therein, the channel being open on a proximal side of the frame member and extending substantially the length of each of the leg members to a point proximate a closed distal end thereof;

the body comprising a peripheral circular frame portion and a solid shell-like cover portion fixed within the frame portion and of a configuration bowed proximally therefrom to provide a bowed proximal surface, such that a central portion of the cover portion always extends proximally further than a peripheral portion of the cover portion;

producing an elongated hole in the bone for each leg of the encapsulation device leg structure;

receiving a distal end of an insertion tool within the central channels of each of the leg members; and

driving each leg of the leg structure of the encapsulation device into the hole provided therefore in the bone to bring a distal surface of the bowed encapsulation device body into adjacency with the bone.

21. The encapsulation device in accordance with claim 1 wherein each of the central channels is substantially tapered along the length thereof.

22. The method in accordance with claim 20 wherein each of the central channels is substantially tapered along the length thereof.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None